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Are Intermediate Endpoints Associated With Serious Adverse Cardiovascular Events: Preliminary Results From The BeAT-HF Trial

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Abstract:
Background: In a randomized controlled trial, baroreflex activation therapy (BAT) improved exercise capacity (6MHW), quality of life (QOL), NYHA Class and NT-proBNP in patients with heart failure with reduced ejection fraction (HFrEF) and was FDA approved under the Breakthrough Devices Program. We examined whether these symptomatic endpoints are associated with cardiovascular serious adverse events, such as such as hospitalization for serious cardiac arrhythmias, hypotension/syncope and MI/angina.
Objective: This analysis compared the event rate of cardiovascular (CV) serious adverse events in the BAT and Control groups.
Methods: The BeAT-HF study included HFrEF patients, currently or recently with NYHA class III symptoms, LVEF ≤ 35%, NT-proBNP <1600 pg/ml, stable optimal medical heart failure management for at least 4 weeks and not class-1 indicated for cardiac resynchronization therapy. Patients were randomized 1:1 to receive BAT plus optimal medical management (BAT group) or optimal medical management alone (Control group). CV serious adverse events (SAE) within six months of follow-up were adjudicated by an independent committee.
Results: Within the first six months, BAT patients had significantly less events in all CV SAE categories than the Control patients, as shown in the Table below.
Conclusion: The positive association between a reduction in symptomatic endpoints and CV serious adverse events observed in the trial support the Breakthrough Device Program of the FDA. The BEAT-HF trial continues in a blinded manner to assess heart failure morbidity and mortality in a pre-specified post-market study to provide further potential evidence of BAT's benefit.

	BAT 125		Control 134			
SAE	Number of Events (# subjects)	Event Rate per patient year of follow-up	Number of Events (# subjects)	Event Rate per patient year of follow-up	Relative Reduction in Event Rate (95% CI)*	p-value**
Cardiac Arrhythmias/ Cardiac Arrest	8 (6)	0.054	18 (12)	0.109	0.50 (-0.14, 0.78)	0.100
Hypotension/ Syncope	2 (2)	0.014	6 (4)	0.036	0.63 (-0.85, 0.92)	0.226
MI/Angina	5 (4)	0.034	10 (10)	0.060	0.44 (-0.63, 0.81)	0.288
Total	**15 (11)**	**0.101**	**34 (22)**	**0.206**	**0.51 (0.10, 0.73)**	**0.023**

*1-BAT / Control; **Poisson regression p-value

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